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SEP - 8 2004

510(k) SUMMARY

1. SUBMITTER:

Scandius Biomedical, Inc.
11A Beaver Brook Road
Littleton, MA 01460

Contact: Eric Bannon, Regulatory Consultant
Date Prepared: June 28, 2004

2. DEVICE:

Trade Name: Scandius ACL Reconstruction System
Classification Name: Fastener, Fixation, Non-Degradable, Soft Tissue
The Product Code: ~~MBI~~ HWC

3. PREDICATE DEVICE:

The predicate device used to determine substantial equivalence for the Scandius ACL Reconstruction System was the Depuy Linx HT.

4. DEVICE DESCRIPTION:

The ACL Reconstruction System consists of a two piece implant designed to fixation soft tissue for ACL reconstruction. The graft block secures the soft tissue graft. A fixation pin placed transversely to the femoral tunnel secures the graft block in place.

The System includes instrumentation to create the bone tunnel and place the device as well as a sterilization tray.

5. INTENDED USE:

The intended use of the Scandius ACL Reconstruction System is for fixation of ligament and tendon grafts in cruciate ligament reconstructions.

6. COMPARISON OF CHARACTERISTICS:

- The devices have the same intended and indication for use, have similar technical characteristics and principles of operation.
- The devices use similar implant materials

- Bench testing demonstrate that any minor technological differences do not raise any new questions of safety and effectiveness.

7. PERFORMANCE DATA:

The following performance data was provided in support of the substantial equivalence determination:

- Mechanical ultimate failure strength

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

SEP - 8 2004

Mr. Eric Bannon
Regulatory Consultant
Scandius BioMedical, Inc.
11A Beaver Brook Road
Littleton, Massachusetts 01460

Re: K041749
Trade/Device Name: Scandius ACL Reconstruction System
Regulation Number: 21 CFR 888.3040
Regulation Name: Smooth or threaded metallic bone fixation fastener
Regulatory Class: II
Product Code: HWC
Dated: June 28, 2004
Received: June 29, 2004

Dear Mr. Bannon:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97) you may obtain. Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,

Celia M. Witten, PhD, MD
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k) Number (if known): K041749

Device Name: Scandius ACL Reconstruction System

Indications for Use: The Scandius ACL Reconstruction System is intended for use in fixation of ligament and tendon grafts in cruciate ligament reconstructions.

(PLEASE DO NOT WRITE BELOW THIS LINE -- CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ✓ OR Over-The-Counter Use ___
(Per 21 C.F.R. 801.109)

(Optional Format 1-2-96)

for Mark N Milkerson

(Division Sign-Off)
Division of General, Restorative, and Neurological Devices

510(k) Number K041749